Enrollment Form
Thyroid (THCA)

Instructions: *The Enrollment Form should be completed for each TCGA qualified case, upon qualification notice from the BCR. All information provided on this form should include activity from the date of initial diagnosis to the most recent date of contact with the patient ("Date of Initial Pathologic Diagnosis" and "Date of Last Contact" on this form).*

Questions regarding this form should be directed to the Tissue Source Site's primary Clinical Outreach Contact at the BCR.

Please note the following definitions for the "Unknown" and "Not Evaluated" answer options on this form.

Unknown: This answer option should only be selected if the TSS does not know this information after all efforts to obtain the data have been exhausted. If this answer option is selected for a question that is part of the TCGA required data set, the TSS must complete a discrepancy note providing a reason why the answer is unknown.

Not Evaluated: This answer option should only be selected by the TSS if it is known that the information being requested cannot be obtained. This could be because the test in question was never performed on the patient or the TSS knows that the information requested was never disclosed.

Tissue Source Site (TSS): _____TSS Identifier: _____ TSS Unique Patient Identifier: _____

Completed By *(Interviewer Name in OpenClinica)*: _____Completed Date: _____

General Information

#	Data Element	Entry Alternatives	Working Instructions
1*	Has this TSS received permission from the NCI to provide time intervals as a substitute for requested dates on this form?	☐ Yes ☐ No	If the answer to this question is yes, time intervals must be provided instead of dates, as indicated throughout this form. Provided time intervals must begin with the date of initial pathologic diagnosis (i.e. biopsy or resection). Only provide interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
2	Is this a prospective tissue collection?	☐ Yes ☐ No	Indicate whether the TSS providing tissue is contracted for prospective tissue collection. If the submitted tissue was collected for the specific purpose of TCGA, the tissue has been collected prospectively. 3088492
3	Is this a retrospective tissue collection?	☐ Yes ☐ No	Indicate whether the TSS providing tissue is contracted for retrospective tissue collection. If the submitted tissue was collected prior to the date the TCGA contract was executed, the tissue has been collected retrospectively. 3088528
Patient Information			
4*	Date of Birth	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	Provide the date the patient was born. 2896950 (Month), 2896952 (Day), 2896954 (Year)
5	Number of Days from Date of Initial Pathologic Diagnosis to Date of Birth	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the patient's date of birth. 3008233 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
6*	Gender	☐ Female ☐ Male	Provide the patient's gender using the defined categories. 2200604

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#	Data Element	Entry Alternatives	Working Instructions
7	Race	☐ American Indian or Alaska Native *A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.* ☐ Asian *A person having origins in any of the original peoples of the far East, Southeast Asia, or in the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.* ☐ White *A person having origins in any of the original peoples of the far Europe, the Middle East, or North Africa.* ☐ Black or African American *A person having origins in any of any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."* ☐ Native Hawaiian or other Pacific Islander: *A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.* ☐ Not Evaluated *Not provided or available.* ☐ Unknown *Could not be determined or unsure.*	Provide the patient's race using the defined categories. 2192199
8	Ethnicity	☐ Not Hispanic or Latino: *A person not meeting the definition of Hispanic or Latino.* ☐ Hispanic or Latino: *A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.* ☐ Not Evaluated *Not provided or available.* ☐ Unknown *Could not be determined or unsure.*	Provide the patient's ethnicity using the defined categories. 2192217
9*	History of Prior Malignancy	☐ Yes ☐ No	Indicate whether the patient was, at any time in their life, diagnosed with a malignancy prior to the diagnosis of the specimen submitted for TCGA. If the patient has had a prior malignancy, an additional form (the "Other Malignancy Form") must be completed for each prior malignancy. If the OMF was completed and submitted with the Initial Case Quality Control Form, the OMF does not need to be submitted a second time. 3382736 If this question cannot be answered because the answer is unknown, the case will be excluded from TCGA. If the patient has a history of multiple diagnoses of basal or squamous cell skin cancer, complete an OMF for the first diagnosis for each of these types.
10*	History of Neo-adjuvant (Pre-Operative) Treatment for Tumor Submitted for TCGA	☐ Yes ☐ No	Indicate whether the patient received neo-adjuvant treatment (radiation, pharmaceutical, or both) prior to the collection of the sample submitted for TCGA. 3382737 Systemic therapy and certain localized therapies (those administered to the same site as the TCGA submitted sample) given prior to the collection of the sample submitted for TCGA is exclusionary.
11	Tumor Status *(at time of last contact or death)*	☐ Tumor free ☐ With tumor ☐ Unknown	Indicate whether the patient was tumor/disease free at the date of last contact or death. 2759550
12*	Vital Status *(at date of last contact)*	☐ Living ☐ Deceased	Indicate whether the patient was living or deceased at the date of last contact. 5
13	Date of Last Contact	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	If the patient is living, provide the date of last contact with the patient (as reported by the patient, medical provider, family member, or caregiver). 2897020 (Month), 2897022 (Day), 2897024 (Year) Do not answer if patient is deceased.

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14	Number of Days from Date of Initial Pathologic Diagnosis to Date of Last Contact	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of last contact. 3008273 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
15	Date of Death	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	If the patient is deceased, provide the date of death. 2897026 (Month), 2897028 (Day), 2897030 (Year)
16	Number of Days from Date of Initial Pathologic Diagnosis to Date of Death	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of death. 3165475 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
17	Thyroid Medical History *(Check all that apply)*	☐ Normal ☐ Lymphocytic Thyroiditis ☐ Nodular Hyperplasia ☐ Unknown ☐ Other, please specify	Provide the patient's thyroid medical history. 3176743
18	Other Thyroid Medical History	_____	If the patient has had a history of thyroid related disease/ disorder(s) and it is not included in the list provided, please describe the patient's thyroid health history. 3179397
19	History of Thyroid Cancer for First Degree Relatives *(Check all that apply)*	☐ Parent ☐ Siblings ☐ Children ☐ Unknown	Provide any known family history of thyroid cancer for first degree relatives only. If the patient had no family history of thyroid cancer, skip this question. 3179002
20	History of Radiation Exposure	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had a history of radiation exposure. 2816350
Pathologic/Prognostic Information			
Pathologic Diagnosis Information			
21*	Primary Site of Disease	☐ Thyroid	Using the patient's pathology/laboratory report, select the anatomic site of disease of the tumor submitted for TCGA. 2735776
22*	Histological Subtype	☐ Thyroid Papillary Carcinoma - Classical/usual ☐ Thyroid Papillary Carcinoma - Follicular (≥ 99% follicular patterned) ☐ Thyroid Papillary Carcinoma - Tall cell (≥ 50% tall cell features) ☐ Other, specify below	Using the patient's pathology/laboratory report, select the histology and/or subtype of the tumor submitted for TCGA. 3081934
23	Other Histological Subtype	_____	If the histological subtype on the pathology/laboratory report does not fall under the provided histological types, describe the histology and/or subtype here. 3124492
24*	Tumor Laterality	☐ Left ☐ Isthmus ☐ Right ☐ Total Thyroid ☐ Bilateral ☐ Thyroid NOS	Using the patient's pathology/laboratory report, indicate the laterality of the tumor. Include all areas of the tumor. 3186750
25*	Tumor Focality	☐ Unifocal ☐ Multifocal	Using the patient's pathology/laboratory report, indicate the Focality of the tumor. Include all areas of the tumor. 3174022
26	Tumor Size	_____ (length) x _____ (width) x _____(depth) cm	Using the patient's pathology/laboratory report, indicate the tumor size. Provide the greatest dimension, including all areas of the tumor. 2764966

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#	Data Element	Entry Alternatives	Working Instructions
27*	Date of Initial Pathologic Diagnosis	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	Provide the date the patient was initially pathologically diagnosed with the malignancy submitted for TCGA. 2896956 (Month), 2896958 (Day), 2896960 (Year)
28	Age at Initial Diagnosis	_____	Provide the age of the patient in years, at the time the patient was initially pathologically diagnosed. 2006657 Only complete this question if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
Lymph Node Status			
29	Preoperative Imaging of Lymph Nodes	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received preoperative imaging of the lymph nodes. 3178301
30	Type of Preoperative Imaging of Lymph Nodes *(Check all that apply)*	☐ Ultrasound ☐ CT with contrast ☐ CT without contrast ☐ MRI with contrast ☐ MRI without contrast ☐ Unknown	If the patient received preoperative imaging of the lymph nodes, indicate what type of imaging was done. 3178310
31	Were Lymph Nodes Examined at the Time of Primary Resection?	☐ Yes ☐ No ☐ Unknown	Indicate whether any lymph nodes were examined at the time of the primary resection. 2200396
32	Number of Lymph Nodes Examined	_____	Provide the number of lymph nodes examined, if one or more lymph nodes were removed. 3
33	Number of Lymph Nodes Positive by H&E light microscopy	_____	Provide the number of lymph nodes positive through hematoxylin and eosin (H&E) staining and light microscopy. 3086388
34	Extrathyroidal Extension	☐ None ☐ Minimal (T3) ☐ Moderate/Advanced (T4a) ☐ Very Advanced (T4b) ☐ Unknown	Indicate whether there was extrathyroidal extension. If there was extrathyroidal extension, provide the type. 3179452
35	Residual Tumor	☐ RX ☐ R0 ☐ R1 (microscopic residual disease) ☐ R2 (gross residual disease) ☐ Unknown	Using the patient's operative report, indicate whether there was residual tumor after the surgical procedure. 2608702
AJCC Staging			
36*	AJCC Cancer Staging Edition	☐ 1st Edition *(1978-1983)* ☐ 2nd Edition *(1984-1988)* ☐ 3rd Edition *(1989-1992)* ☐ 4th Edition *(1993-1997)* ☐ 5th Edition *(1998-2002)* ☐ 6th Edition *(2003-2009)* ☐ 7th Edition *(2010-present)*	Please select the AJCC Cancer Staging Edition used to answer the following questions. 2722309
37*	Pathologic T Stage	☐ TX ☐ T0 ☐ Tis ☐ T1 ☐ T1a ☐ T1b ☐ T1c ☐ T2 ☐ T2a ☐ T2b ☐ T3 ☐ T3a ☐ T3b ☐ T4 ☐ T4a ☐ T4b	Using the patient's pathology/laboratory report, select the code for the pathologic T (primary tumor) defined by the American Joint Committee on Cancer (AJCC). 3045435
38*	Pathologic N Stage	☐ NX ☐ N0 ☐ N1 ☐ N1a ☐ N1b ☐ N1c ☐ N2	Using the patient's pathology/laboratory report, select the code for the pathologic N (nodal) defined by the American Joint Committee on Cancer (AJCC). 3203106
39*	Pathologic M Stage	☐ MX ☐ M0 ☐ M1	Using the patient's pathology/laboratory report, select the code for the pathologic M (metastasis) defined by the American Joint Committee on Cancer (AJCC). 3045439

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40*	Stage	☐ Stage I ☐ Stage IIA ☐ Stage IIB ☐ Stage IIC ☐ Stage III ☐ Stage IIIA ☐ Stage IIIB ☐ Stage IIIC ☐ Stage IV	Using the patient's pathology/laboratory report, select the stage defined by the American Joint Committee on Cancer (AJCC). 3203222
Metastatic Tumor *(Complete when applicable)*			
41	If patient had metastatic disease, how was it confirmed? *(Check all that apply)*	☐ RAI-avid ☐ Biopsy Proven ☐ Imaging Suspected ☐ Unknown ☐ Other, please specify	If the patient had a metastatic tumor, provide the method used to confirm the metastatic diagnosis. If the patient did not have a metastatic tumor, skip this and the following metastatic questions. 3178364
42	Metastatic Diagnosis Confirmed by Other	_____	If the patient had a metastatic tumor and the method used to confirm the diagnosis is not included in the provided list, please describe the method. 3178376
43	If patient had metastatic disease, provide the site. *(Check all that apply)*	☐ Lung ☐ Bone ☐ Unknown ☐ Other, please specify	If the patient had a metastatic tumor associated with the diagnosis of the tumor submitted for TCGA, provide the site of the metastasis. If there was more than one metastatic site, select all that apply. 2967298
44	Other Site of Metastatic Tumor	_____	If the site of the metastasis was not included in the list provided, please provide the site. 3178387
Genotypic Analysis			
45	Genotypic Analysis Detected	☐ Yes ☐ No ☐ Unknown	Indicate whether genotypic analysis was detected for the patient. 3179001
46	Reason(s) for Genotypic Analysis not Detected	**BRAF Mutation**: ☐ No Mutation ☐ Not Performed ☐ Unknown **RAS Mutation**: ☐ No Mutation ☐ Not Performed ☐ Unknown **RET/PTC Rearrangement**: ☐ No Mutation ☐ Not Performed ☐ Unknown	If genotypic analysis was NOT detected, indicate why for each mutation/rearrangement. 3179383
47	BRAF Mutation Result	_____	Based on genotypic analysis performed, provide the BRAF mutation results for this patient. If the patient's results are unknown or if genotypic analysis was not performed, skip this question. 3179257
48	RAS Mutation Result	_____	Based on genotypic analysis performed, provide the RAS mutation results for this patient. If the patient's results are unknown or if genotypic analysis was not performed, skip this question. 3179266
49	RET/PTC Rearrangement Result	_____	Based on genotypic analysis performed, provide the RET/PTC rearrangement mutation results for this patient. If the patient's results are unknown or if genotypic analysis was not performed, skip this question. 3179271
50	Other Genotypic Analysis Results	_____	Based on genotypic analysis performed, provide any other mutation results for this patient. If the patient's results are unknown or if genotypic analysis was not performed, skip this question. 3179278
Treatment Information			
51*	Adjuvant (Post-Operative) Radiation Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative radiation therapy. 2005312 If the patient did have adjuvant radiation, the Radiation Supplemental Form should be completed.

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#	Data Element	Entry Alternatives	Working Instructions
52*	Adjuvant (Post-Operative) Pharmaceutical Therapy	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had adjuvant/ post-operative pharmaceutical therapy. 3397567 If the patient did have adjuvant pharmaceutical therapy, the Pharmaceutical Supplemental Form should be completed.
Adjuvant I-131 Therapy and Radiation Therapy (XRT) *For Primary Tumor*			
53	I-131 Treatment: Method of preparation	☐ rhTSH ☐ Thyroxine withdrawal ☐ Patient did not receive I-131treatment ☐ Unknown	If the patient received I-131 therapy for the primary tumor, indicate the method used. 3232952 If the patient did NOT receive I-131 therapy for the primary tumor, related questions can be skipped.
54	I-131 Treatment: Dose of First Treatment	_____	If the patient received I-131 therapy for the primary tumor, provide the dose of the first treatment. 3232898
55	I-131 Treatment: Subsequent Treatments	_____	If the patient received I-131 therapy for the primary tumor, detail subsequent treatments. 3232904
56	I-131 Treatment: Total Cumulative Dose	_____	If the patient received I-131 therapy for the primary tumor, provide the total cumulative dose. 3232906
57	Radiation Therapy (XRT): Method of preparation	☐ Hyperfractionated ☐ IMRT ☐ Patient did not receive external radiation therapy ☐ Unknown	If the patient received radiation therapy for the primary tumor, indicate the method of preparation. 3232960
58	Radiation Therapy (XRT): Dose Administered	_____	If the patient received radiation therapy for the primary tumor, provide the dose administered. 3232933
59	Radiation Therapy (XRT): Radiation Sensitizers Administered	☐ Yes ☐ No ☐ Unknown	If the patient received radiation therapy for the primary tumor, indicate whether or not radiation sensitizers were administered. 3232932
Clinical Status after Surgery			
60	Clinical Status Within Three (3) Months of Surgery	☐ No Imaging Evidence of Disease ☐ Persistent Locoregional Disease ☐ Persistent Distant Metastases ☐ Not Evaluated ☐ Unknown	Indicate the patient's clinical status within three months of the surgery related to thyroid carcinoma submitted for TCGA. 3186684
New Tumor Event Information *Complete this section if the patient had a new tumor event. If the patient did not have a new tumor event (or if the TSS does not know) indicate this in the question below, and the remainder of this section can be skipped.*			
61	New Tumor Event After Initial Treatment?	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient had a new tumor event (e.g. metastatic, recurrent, or new primary tumor) after initial treatment. 3121376 If the patient did not have a new tumor event or if this is unknown, the remaining questions can be skipped.
62	Type of New Tumor Event	☐ Locoregional ☐ Distant Metastasis ☐ New Primary Tumor ☐ Biochemical Evidence of Disease	Indicate whether the patient's new tumor event was a locoregional recurrence, a distant metastasis or a new primary tumor. A new primary tumor is a tumor with a different histology as the tumor submitted to TCGA. 3119721
63	Site of New Tumor Event	☐ Lung ☐ Lymph Node(s) ☐ Bone ☐ Unknown ☐ Soft Tissue ☐ Other, specify	Indicate the site of this new tumor event. 3108271
64	Other Site of New Tumor Event	_____	If the site of the new tumor event is not included in the provided list, describe the site of this new tumor event. 3128033

#	Data Element	Entry Alternatives	Working Instructions
65	Date of New Tumor Event	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	If the patient had a new tumor event, provide the date of diagnosis for this new tumor event. 3104044 (Month), 3104042 (Day), 3104046 (Year)
66	Number of Days from Date of Initial Pathologic Diagnosis to Date of New Tumor Event After Initial Treatment	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease to the date of new tumor event after initial treatment. 3392464 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.
67	New Tumor Event Diagnosis Confirmed By	☐ Imaging ☐ Pathology ☐ Unknown	If the patient had a new tumor event, provide the method used to confirm this diagnosis. 3186701
68	Evidence of Histologic Progression	☐ Yes ☐ No ☐ Unknown	Indicate whether the new tumor event had evidence of histologic progression. 3181376
69	Type of Histologic Progression	☐ Poorly Differentiated ☐ Anaplastic ☐ Unknown ☐ Other, specify	If the new tumor event had evidence of histologic progression, indicate the type of evidence. 3181384
70	Other Type of Histologic Progression	_____	If the histologic progression for the new tumor event is not included in the list provided, describe the type of progression. 3181387
71	If lymph nodes are positive, specify site(s) *Check all that apply*	☐ Central (levels 6-7) ☐ Lateral (levels 2-5) ☐ Unknown ☐ Other, specify	If the patient had positive lymph nodes, provide the site of the positive nodes. 3186207
72	Other Site of Positive Lymph Nodes	_____	If the patient had positive lymph nodes and the site is not included in the provided list, please indicate the location. 3185693
73	Additional Therapy Required for New Tumor Event *Check all that apply*	☐ No Additional Therapy ☐ Surgery ☐ RAI Therapy ☐ EBRT ☐ Pharmaceutical Therapy ☐ Unknown	Indicate they type of additional therapy required for the new tumor event. 3185186
74	Additional treatment for New Tumor Event: *Surgery*	☐ Yes ☐ No ☐ Unknown	Using the patient's medical records, indicate whether the patient had surgery for the new tumor event in question. 3427611
75	Date of Additional Surgery for New Tumor Event	___ ___ ___ ___ ___ ___ ___ ___ *Month* *Day* *Year*	If the patient had surgery for the new tumor event, provide the date this surgery was performed. 3427612 (Month), 3427613 (Day), 3427614 (Year)
78	Number of Days from Date of Initial Pathologic Diagnosis to Date of Additional Surgery for New Tumor Event	_____	Provide the number of days from the date the patient was initially diagnosed pathologically with the disease described on this form to the date of additional surgery for new tumor event. 3008335 Only provide Interval data if you have received permission from the NCI to provide time intervals as a substitute for requested dates on this form.

#	Data Element	Entry Alternatives	Working Instructions
79	Additional treatment for New Tumor Event: *Radiation Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received radiation treatment for this new tumor event. 3427615
80	Additional treatment for New Tumor Event: *Pharmaceutical Therapy*	☐ Yes ☐ No ☐ Unknown	Indicate whether the patient received pharmaceutical treatment for this new tumor event. 3427616
Adjuvant I-131 Therapy and Radiation Therapy (XRT) *For New Tumor Event*			
81	I-131 Treatment: Method of preparation	☐ rhTSH ☐ Thyroxine withdrawal ☐ Patient did not receive I-131treatment ☐ Unknown	If the patient received I-131 therapy for the new tumor event, indicate the method used. 3232952 NOTE: If the patient did NOT receive I-131 therapy for the new tumor event, related questions can be skipped.
82	I-131 Treatment: Dose of First Treatment	_____	If the patient received I-131 therapy for the new tumor event, provide the dose of the first treatment. 3232898
83	I-131 Treatment: Subsequent Treatments	_____	If the patient received I-131 therapy for the new tumor event, detail subsequent treatments. 3232904
84	I-131 Treatment: Total Cumulative Dose	_____	If the patient received I-131 therapy for the new tumor event, provide the total cumulative dose. 3232906
85	Radiation Therapy (XRT): Method of preparation	☐ Hyperfractionated ☐ IMRT ☐ Patient did not receive external radiation therapy ☐ Unknown	If the patient received radiation therapy for the new tumor event, indicate the method of preparation. 3232960
86	Radiation Therapy (XRT): Dose Administered	_____	If the patient received radiation therapy for the new tumor event, provide the dose administered. 3232933
87	Radiation Therapy (XRT): Radiation Sensitizers Administered	☐ Yes ☐ No ☐ Unknown	If the patient received radiation therapy for the new tumor event, indicate whether or not radiation sensitizers were administered. 3232932

_____ _____ ___ ___/ ___ ___/ ___ ___ ___ ___

Principal Investigator or Designee Signature | Print Name | Date